

### REMARKS

In response to the October 26, 2007 Final Office Action, Applicant submits the following remarks. Currently, claims 1-24 are pending in the application with claims 1, 3 and 16 being independent. Claims 1, 3, and 16 have been amended, support for which can be found in canceled claims 4 and 17. Claim 5 was amended to deleted now duplicative subject matter. Claims 4 and 17 have been cancelled without prejudice or disclaimer. Claims 25, 26 and 27 are new. The support for these claims can be found in Applicant's specification at least in paragraph [0005], among other places.

### Objections

In the Final Office Action, the Examiner objected to oath/declaration as being defective and stated that the Declaration does not contain acknowledgement with regard to the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 C.F.R. 1.56. Applicant respectfully submits a copy (as obtained from PAIR) of the executed declaration form PCT/RO/101, that includes the following statement "I hereby acknowledge the duty to disclose information that is known by me to be material to patentability as defined by 37 C.F.R. 1.56...". (see, Exhibit 1). Additionally, Applicant submits an executed Declaration that contains a similar statement on its first page. (See, Exhibit 2). As such, this objection is now moot. The Examiner is requested to withdraw this objection.

### 35 USC §102

In the Final Office Action, the Examiner has rejected claims 1-3, 7, 16 and 20 under 35 USC § 102(b) as being anticipated by U.S. Patent No. 6,159,211 to Boriani (hereinafter,

“Boriani”). Applicant respectfully disagrees and traverses this rejection, and requests that the rejection be withdrawn for at least the following reasons.

Amended claims 1, 3, and 16 recite, *inter alia*, a rigid cage formed in an annular configuration of a biologically inert material, and an annular side wall extending between the surfaces, a plurality of raised ridges projecting outwardly from each of the perimeter surfaces for engaging the spinal column and securing the assembly therein and disposed at offset angles with respect to each other, wherein at least one of said perimeter surfaces of said cage defines a plurality of indexing members thereon and wherein said cage assembly includes at least one spacing element adapted to be secured to said one cage for the stacked attachment of said cage with a second cage, said indexing members cooperating with portions of said spacing element for axially aligning said spacing element with said one cage.

As understood by Applicant, Boriani discloses a surgical prosthetic modular device that can be used singularly or stacked together to replace excised vertebral tissue. (Boriani, Abstract): Boriani fails to disclose that the perimeter surfaces of the cage define a plurality of indexing members thereon and the cage assembly includes at least one spacing element adapted to be secured to the cage, as recited in claims 1, 3, and 16. In contrast, Boriani’s cages are meant to be stacked directly on top of each other as indicated by the statement: “[t]he ridges 24, 25 are designed to interdigitate to form a stack.” (Boriani, column 3, lines 45-46) and as shown in Boriani’s Figure 2. (emphasis supplied). As such, Boriani fails to disclose all elements of claims 1, 3, and 16 and, hence does not anticipate them. Applicant respectfully requests allowances of these claims. Claims 2-3, 7, and 20 are dependent on the respective claims 1, 3, and 16. As such, claims 2-3, 7, and 20 are not anticipated by Boriani for at least the reasons stated above with

regard to claims 1, 3, and 16. Thus, this rejection is respectfully traversed, and the Examiner is requested to reconsider and withdraw this rejection of claims 1-3, 7, 16, and 20.

In the Final Office Action, the Examiner has rejected claims 3-6, 8-10, 12-19, 21 and 23 under 35 USC § 102(e) as being anticipated by U.S. Publication No. 2004/0073314 to White, et al, (hereinafter, "White"). Applicant respectfully disagrees and traverses this rejection, and requests that the rejection be withdrawn for at least the following reasons.

As understood by Applicant, White discloses a vertebral replacement device for supporting adjacent vertebrae and that includes a vertebral body member having at least one upper or lower disc replacement member engaged thereto at one end thereof. (White, Abstract). The Examiner alleged that White discloses a "spacing element 310" which is equivalent to Applicant's claimed spacing element. However, White's "spacing element" is referred to by White as a "vertebral body member" and is not at all a spacing element. Instead, White's member is a complete and very large structure that replaces an entire vertebral body. Applicant respectfully submits that White's vertebral body member is not an equivalent structure to that of Applicant's spacing element since the purpose and functions of the structures are completely different. Further, the Examiner alleges that "the indexing members cooperate with indexing members in the form of pins 316-319 on the spacing element 310." (Final Office Action, page 4). White's vertebral replacement device 300 includes vertebral body member 310 and upper disc replacement member 400 and a lower disc replacement member 401 both engaged with the device 300. (White, para. [0083], Figure 13). The vertebral body 310 includes first and second upper extensions 316 and 318 as well as first and second lower extensions 317, 319, which cooperate with the respective disc replacement members 400, 401. (White, para. [0091], Figure 13). This is different than the present invention's perimeter surfaces of said cage that define a

plurality of indexing members thereon and wherein said cage assembly includes at least one spacing element adapted to be secured to said one cage for the stacked attachment of said cage with a second cage, said indexing members cooperating with portions of said spacing element for axially aligning said spacing element with said one cage, as recited in claim 3. Instead, White's vertebral body 310 has projecting pins or extensions that cooperate with the disc replacement members, as opposed to be the other way around, as recited in claim 3.

Further, in the Final Office Action, the Examiner alleges that White's apertures 418 and 420 in its disc replacement member 400 are comparable to both the plurality of indexing members and the pair of axially aligned openings recited in claim 3 of the present application. Clearly, the indexing members and the axially aligned openings of the present application's claim 3 are two entirely different elements that serve different purposes, as recited in the claims. Further, White has indicated that its disc replacement member 400 can be provided with a hollow interior or one or more openings that can be packed with bone growth material. (White, para. [0092]). Thus, at best, for the sake of an example only, the apertures 418 and 420 may be comparable to the pair of axially aligned openings recited in claim 3. As such, the Examiner's comparison is improper and White fails to disclose the indexing members recited in claim 3. White does not anticipate claim 3 and, thus, this rejection is respectfully traversed.

Claims 4-6, 8-10, 12-19, 21, and 23 are not anticipated by White for at least the reasons stated above with regard to claim 3. Thus, the rejection of claims 4-6, 8-10, 12-19, 21, and 23 is respectfully traversed. The Examiner is requested to reconsider and withdraw the rejection of claims 4-6, 8-10, 12-19, 21, and 23.

35 U.S.C. §103

The Examiner bears the initial burden of factually supporting any prima facie conclusion of obviousness. If the Examiner does not produce a prima facie case, Applicant is under no obligation to submit evidence of non-obviousness. MPEP §2142. According to MPEP §2143, to establish a prima facie case of obviousness, three basic criteria must be met. First, there must be a reasonable expectation of success. Second, the prior art reference (or references when combined) must teach or suggest all the claim limitations. Finally, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings.

In the Final Office Action, the Examiner has rejected claim 11 under 35 U.S.C. § 103 as being unpatentable over White. Applicant respectfully disagrees and traverses this rejection, and requests that the rejection be withdrawn for at least the following reasons.

Applicant respectfully submits that the Examiner has not met his burden in proving a prima facie case of obviousness. As explained above, White does not disclose all the claimed elements, as currently recited in the amended claim 3. As such, White fails to render claim 11 obvious for at least the reasons stated above with regard claim 3.

Additionally, the Examiner has admitted that White, et al. does not disclose “a pair of resilient members on opposite sides of the spacer element.” Claim 11, recites, *inter alia*, “...a second pair of resilient locking members...” (emphasis supplied). To support his argument and illustrate this missing element, the Examiner makes the following statement, “mere duplication of essential working parts of a device involves only routine skill in the art (Final Office Action, page 5). However, White fails to even disclose a pair of locking members. Instead, White only

discloses engagement members 320, 321, where each includes a projection or engaging portion 352 and a stem 350 connected or integrally formed with end surface 314 of body 312 (White, para. [0089]). Stem 350 has a thickness that allows engaging member 320 to deflect inwardly toward longitudinal axis 302 in response to a force applied to engaging portion 352. (White, para. [0089]). However, nowhere does White disclose that any portion of its vertebral replacement device is a “locking member”, contrary to the recitation of claim 11. Thus, White fails to disclose, teach or suggest all of the claimed elements of claim 11. Thus, this rejection is respectfully traversed. Applicant respectfully requests that the Examiner withdraw this rejection and that claim 11 is allowed.

In the Final Office Action, the Examiner has rejected claim 22 under 35 U.S.C. § 103 as being obvious over Boriani in view of U.S. Patent No. 5,192,327 to Brantigan (hereinafter, “Brantigan”). Applicant respectfully disagrees and traverses this rejection, and requests that the rejection be withdrawn for at least the following reasons.

Applicant respectfully submits that the Examiner has not met his burden in proving a prima facie case of obviousness since the Examiner, in part, has not shown that Boriani in view of Brantigan teaches or suggests all of the features of claim 22. As stated above, Boriani fails to disclose “a plurality of indexing members and at least one spacing element” as recited in claim 16. Boriani fails to disclose “at least one of said perimeter surfaces of said cage defines a plurality of indexing members thereon and wherein said cage assembly includes at least one spacing element adapted to be secured to said one cage for the stacked attachment of said cage with a second cage, said indexing members cooperating with portions of said spacing element for axially aligning said spacing element with said one cage,” as recited in claim 16. Brantigan fails to cure the deficiencies of Boriani. As understood by Applicant, Brantigan discloses a surgical

prosthetic implant that is used singularly or stacked together to support and fuse together adjacent vertebrae or to totally or partially replace one or more vertebrae in a vertebral column. (Brantigan, Abstract). Brantigan further includes ridges that are formed longitudinally across the end faces of the implant. (Brantigan, FIG. 1, Col. 4, lines 15-19). The ridges further define peaks and valleys that are configured to allow stocking of one implant on top of the other. (Brantigan, FIGS. 1-5). Thus, Brantigan ridges are parallel to each other. This is different than the present invention, where raised ridges are disposed at offset angles with respect to each other, as recited in claim 16. Further, Brantigan also fails to disclose, teach or suggest, at least one of said perimeter surfaces of said cage defines a plurality of indexing members thereon and wherein said cage assembly includes at least one spacing element adapted to be secured to said one cage for the stacked attachment of said cage with a second cage, said indexing members cooperating with portions of said spacing element for axially aligning said spacing element with said one cage, as recited in claim 16. As such, Brantigan fails to disclose all elements of claim 16. As such, claim 22 is patentable over Boriani, Brantigan or their combination for at least the reasons stated above with regard to claim 16.

Further, the Examiner has submitted no evidence on the record of any reasonable expectation of success, or any suggestion or motivation to combine reference teachings. Applicant respectfully submits that the Examiner has not met his burden for rejecting claim 22 and requests reconsideration and withdrawal of this obviousness rejection as required by MPEP §2143.

Thus, claim 22 is not rendered obvious by the combination of Boriani and Brantigan for at least the reasons stated above with regard to claim 16. As such, the rejection of claim 22 is

respectfully traversed. The Examiner is requested to reconsider and withdraw his rejection of claim 22.

In the Final Office Action, the Examiner has rejected claim 24 under 35 U.S.C. § 103 as being obvious over White in view of Brantigan. Applicant respectfully disagrees and traverses this rejection, and requests that the rejection be withdrawn for at least the following reasons.

Claim 24 is dependent on claim 17, which in turn depends on claim 16. Claim 24 recites, *inter alia*, “cage assembly and said spacing element are substantially oval-shaped.” As explained above, White does not disclose a spacing element, but a “vertebral body member” which is not at all a spacing element, but a complete and very large structure which replaces an entire vertebral body. Additionally, even if Brantigan discloses an oval shaped cage, it fails to disclose an oval-shaped spacing element. Thus, neither White, Brantigan, nor their combination of White and Brantigan disclose, teach or suggest all elements of claim 24.

Additionally, the Examiner has submitted no evidence on the record of any reasonable expectation of success, or any suggestion or motivation to combine reference teachings. Applicant respectfully submits that the Examiner has not met his burden for rejecting claim 24 and requests reconsideration and withdrawal of this obviousness rejection as required by MPEP §2143. As such, the rejection of claim 24 is respectfully traversed. The Examiner is requested to reconsider and withdraw his rejection of claim 24.

New claims 25-27 are patentable over the above-discussed references for at least the reasons stated above with regard to claims 1, 3, and 16.



**Conclusion**


No new matter has been added. The claims currently presented are proper and definite. Allowance is accordingly in order and respectfully requested. However, should the Examiner deem that further clarification of the record is in order, we invite a telephone call to the Applicants' undersigned attorney to expedite further processing of the application to allowance.

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (212) 935-3000.

The Commissioner is authorized to charge any fees that may be due to the undersigned's account, Deposit Account No. **50-0311**, Reference No. Reference No. **26786-520-NATL**. Please address all correspondence to Customer Number **35437**.

Dated: February 25, 2008

Respectfully submitted,



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## **EXHIBIT 1**

**Box No. VIII (iv) DECLARATION: INVENTORSHIP** (only for the purposes of the designation of the United States of America)  
*This declaration must conform to the following standardized wording provided for in Section 214; see Notes to Boxes Nos. VII, VIII (i) to (iv) (in general) and the specific Notes to Box No. VIII (iv). If this Box is not used, this sheet should not be included in the request.*

**Declaration of inventorship (Rules 4.17(iv) and 5181r.1(n)(iv))  
 for the purposes of the designation of the United States of America:**

I hereby declare that I believe I am the original, first and sole (if only one inventor is listed below) or joint (if more than one inventor is listed below) inventor of the subject matter which is claimed and for which a patent is sought.

This declaration is directed to the international application of which it forms a part (if filing declaration with application).

This declaration is directed to international application No. PCT/..... (if furnishing declaration pursuant to Rule 26ter).

I hereby declare that my residence, mailing address, and citizenship are as stated next to my name.

I hereby state that I have reviewed and understand the contents of the above-identified international application, including the claims of said application. I have identified in the request of said application, in compliance with PCT Rule 4.10, any claim to foreign priority, and I have identified below, under the heading "Prior Applications," by application number, country or Member of the World Trade Organization, day, month and year of filing, any application for a patent or inventor's certificate filed in a country other than the United States of America, including any PCT international application designating at least one country other than the United States of America, having a filing date before that of the application on which foreign priority is claimed.

Prior Applications: .....

I hereby acknowledge the duty to disclose information that is known by me to be material to patentability as defined by 37 C.F.R. § 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the PCT international filing date of the continuation-in-part application.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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Inventor's Signature: [Signature]  
 (if not contained in the request, or if declaration is corrected or added under Rule 26ter after the filing of the international application. The signature must be that of the inventor, not that of the agent)

Date: 12/2/04  
 (of signature which is not contained in the request, or of the declaration that is corrected or added under Rule 26ter after the filing of the international application)

Name: .....

Residence: .....  
 (city and either US state, if applicable, or country)

Mailing Address: .....

Citizenship: .....

Inventor's Signature: .....  
 (if not contained in the request, or if declaration is corrected or added under Rule 26ter after the filing of the international application. The signature must be that of the inventor, not that of the agent)

Date: .....  
 (of signature which is not contained in the request, or of the declaration that is corrected or added under Rule 26ter after the filing of the international application)

☐ This declaration is continued on the following sheet, "Continuation of Box No. VIII (iv)".

**Box No. VIII (iii) DECLARATION OF ENTITLEMENT TO CLAIM PRIORITY**

*The declaration must conform to the standardized wording provided for in Section 213; see Notes to Boxes Nos. VIII, VIII (i) to (v) (in general) and the specific Notes to Box No. VIII (iii). If this Box is not used, this sheet should not be included in the request.*

Declaration as to the applicant's entitlement, as at the international filing date, to claim the priority of the earlier application specified below, where the applicant is not the applicant who filed the earlier application or where the applicant's name has changed since the filing of the earlier application (Rules 4.17(iii) and 51bis.1(a)(iii)):

in relation to this international application,

PROSSER, Michael D. is entitled to claim priority of earlier application  
No. 60/526,241, US, filed 2 December 2003 (02.12.03)

by virtue of the following:

the applicant is the inventor of the subject matter for which protection was sought by way  
of the earlier application.

This declaration is made for the purposes of the following designations for national and/or  
regional patents: US

☐ This declaration is continued on the following sheet, "Continuation of Box No. VIII (iii)".

*The declaration must conform to the standardized wording provided for in Section 212; see Notes to Boxes Nos. VIII, VIII (i) to (v) (in general) and the specific Notes to Box No. VIII (ii). If this Box is not used, this sheet should not be included in the request.*

Declaration as to the applicant's entitlement, as at the international filing date, to apply for and be granted a patent (Rules 4.17(ii) and 51bis.1(a)(ii)), in a case where the declaration under Rule 4.17(iv) is not appropriate:

in relation to this international application,

ALPHATEC MANUFACTURING, INC. is entitled to apply for and be granted a patent by virtue of the following:

An assignment from PROSSER, Michael D., 5166 Whitman Way #208, Carlsbad, CA 92008, United States of America

to ALPHATEC MANUFACTURING, INC., dated 2 December 2004 (02.12.04)

This declaration is made for the purposes of all designations, except the designation of the United States of America

☐ This declaration is continued on the following sheet, "Continuation of Box No. VIII (ii)".

## **EXHIBIT 2**

## **EXHIBIT 2**